UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA ex rel. SUSAN HUTCHESON and PHILIP BROWN, Plaintiffs, v. BLACKSTONE MEDICAL, INC., Defendant.	CIVIL ACTION NO. 06-11771-WGY

UNITED STATES' STATEMENT OF INTEREST
REGARDING DEFENDANT'S MOTION TO DISMISS

In its Motion to Dismiss the Relators' Amended Complaint ("BMI's Motion"), defendant Blackstone Medical, Inc. ("BMI") argues, among other things, that even if it paid illegal kickbacks to surgeons, and even if those kickbacks induced the surgeons to perform surgery on Medicare beneficiaries using BMI devices, BMI would be insulated from liability under the False Claims Act ("FCA"), 31 U.S.C. § 3729, *et seq.*, by the fact that the claims for payment for those surgeries were presented to Medicare by innocent third parties who were unaware of the kickbacks.

Pursuant to 28 U.S.C. § 517 (providing for Department of Justice participation in any federal court litigation to attend to the interests of the United States), the United States respectfully submits this Statement of Interest to address certain discrete legal issues raised by BMI's Motion.[1] In this brief, the government wishes to address three legal arguments raised in

[1] The United States has not intervened in this *qui tam* action under the False Claims Act, 31 U.S.C. §§ 3729-3733 (FCA), and is not a formal party to the case, but is the primary real party in interest. *United States ex rel. Eisenstein v. City of New York*, 129 S. Ct. 2230, 2232-

BMI's Motion. First, contrary to BMI's position, the fact that the hospitals that ultimately submitted the claims may not have known about the kickbacks is not relevant to whether the claims are false or fraudulent under the FCA. A person may be liable under the "causes to be presented" prong of the FCA even when the false claim at issue is submitted to the government by an innocent third party, if the submission was the reasonably foreseeable result of a defendant's actions.

Second, the payment of kickbacks in the chain of causation for the claim renders the claim false under the FCA because it is contrary to express certification of compliance and because compliance with the laws prohibiting such kickbacks is a condition of the government's payment.

Third, contrary to BMI's position, there is no *per se* rule that a plaintiff must identify specific false claims that were submitted to the government to satisfy Federal Rule of Civil Procedure 9(b) (hereinafter, "9(b)"). As recently clarified by the First Circuit, a plaintiff does not need to "provide details that identify particular false claims for payment" in order to satisfy 9(b). So long as the complaint provides "factual or statistical evidence to strengthen the inference of fraud beyond a possibility, " the requirements of 9(b) can be met. *See United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 2009 WL 2450716 at * 16 (1st Cir. 2009).

I. STATUTORY BACKGROUND

A. The False Claims Act

A violation of the FCA occurs, *inter alia*, when *any person* "knowingly presents, or

---

2237 (2009). The United States is entitled to a share of not less than 70 percent of any monies recovered through this action, 31 U.S.C. § 3730(d)(2), and has a substantial interest in the proper interpretation and application of the FCA, the government's primary tool to combat fraud. H.R. Rep. No. 99-660 at 18 (1986).

causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. 3729(a)(1).[2] Any person who violates the FCA is liable to the United States for civil penalties and three times the amount of damages that the government sustains "because of the act of that person. . ." 31 U.S.C. §3729(a)(1).

B. The Anti-Kickback Statute

The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) ("AKS"), prohibits *anyone* from, *inter alia*, knowingly and willfully offering to pay or paying any remuneration to another person to induce that person to purchase, order, or recommend any good or item for which payment may be made in whole or in part by the Medicare program. 42 U.S.C. § 1320a-7b(b). In addition to criminal penalties, any violator of the AKS may be subject to exclusion from participation in federal health care programs, 42 U.S.C. § 1320a-7(b)(7), civil monetary penalties of up to $50,000 per violation, 42 U.S.C. § 1320a-7a(a)(7), assessment of up to three times the amount of remuneration paid, 42 U.S.C. 1320a-7a(a), and liability under the FCA.

II. ARGUMENT

A. BMI's Payment Of Kickbacks Rendered The Claims For Payment False

Compliance with the AKS is a condition of payment under the Medicare program, and that condition applies to *anyone*, not just the entity submitting a claim to the government. As the First Circuit and numerous other courts have held, the existence of an AKS violation in the chain of causation renders a claim non-payable and therefore false under the FCA, despite the entity who is submitting the claim. *See Duxbury*, 2009 WL 2450716 at *14-15 (holding the complaint

[2] The FCA, 31 U.S.C. § 3729-3733, has been amended and renumbered pursuant to the passage of the Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, 123 Stat. 1617. The changes relevant here, however, apply prospectively, so do not apply to the case at bar.

met (9)b requirements even where it did not allege that the defendant "*itself* submitted false claims to the government, but that, through [the defendant's] illegal kickbacks, false claims to the Medicare Program were filed by medical providers [including hospitals and cancer treatment centers] for reimbursement of the defendant's drug, with no discussion of express certification); *United States v. Rogan*, 517 F.3d 449, 452 (7th Cir. 2008) (upholding FCA judgment and noting that "paying kickbacks has a good probability of affecting" the government's decision to pay resulting claims); *United States ex rel. McNutt v. Haleyville Medical Supplies*, 423 F.3d 1256, 1259-1260 (11th Cir. 2005) (imposing FCA liability on defendant based on knowing violation of AKS and submission of claims for Medicare reimbursement, without any discussion of expressly false certifications); *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F. Supp.2d 12, 18 (D. Mass. 2007) ("I conclude that the FCA is violated when a Medicaid claim is presented to the state government in violation of the Anti-Kickback statute, even if there is no express certification of compliance with the statute."); *United States ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F.Supp.2d 35, 43 (D. Mass. 2000) (allegations that rebates offered in return for referrals violated the AKS were sufficient to state an FCA claim); *United States ex rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F. Supp.2d 28, 32-34 (D.D.C. 2003) (applying implied certification theory to recognize potential FCA liability based upon alleged violation of AKS); *United States ex rel. Pogue v. Diabetes Treatment Centers of America*, 238 F. Supp.2d 258, 264 (D.D.C. 2002) (affirming prior holding that "Relator's allegation that the government would not have paid the claims submitted if it had known of the alleged kickback and Stark law violations was sufficient to state a False Claims Act claim."). *Cf. United States ex rel. Mikes v. Straus*, 274 F.3d 687, 699 (2d Cir. 2001) (recognizing implied certification as a valid theory of recovery when compliance is express condition of payment). Thus, as the case

law clearly demonstrates, if the Relators can establish that BMI violated the AKS, they will have established that any claims for Medicare or Medicaid reimbursement that were tainted by those kickbacks were "false" within the meaning of the FCA.

B. A Claim's Falsity Does Not Depend On The Presenter's Knowledge Of Such Falsity

1. The FCA Imposes Liability For Causing False Claims Through Others

The FCA expressly imposes liability on two distinct categories of actors: any person who knowingly *presents* a *false* claim, *or* any person who knowingly *causes the presentation* of a *false* claim (or a statement in support thereof). 31 U.S.C. § 3729(a)(1) and (a)(2). If falsity depended solely on the knowledge of the party submitting the claim, the concept of *causing* a *false* claim to be submitted would be superfluous; under such a reading of the statute, the only claims that could ever be false would be those that are submitted by the wrongdoer himself. This reading, however, would disregard the basic principle of statutory construction: that each word in a statute must be given its own meaning.

Such an interpretation would also contravene the longstanding and widely held proposition that the FCA reaches claims that are rendered false by one party, but submitted to the government by another. In *United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943), the Supreme Court held that an illegal scheme to defraud the government renders the resulting downstream claims false notwithstanding that the parties that submitted the claims were innocent, both in terms of their knowledge of the illegal scam and insofar as none participated in the illegal scheme to rig bids. As the Court stated:

> By their conduct, the [defendants] thus caused the government to pay *claims of the local sponsors* in order that they might in turn pay [defendants] under contracts found to have been executed as the result of the fraudulent bidding . . . . These funds are as much in need of protection from fraudulent claims as any other federal

> money, *and the statute does not make the extent of their safeguard dependent upon the bookkeeping devices used for their distribution*. The Senatorial sponsor of this bill broadly asserted that its object was to provide protection against those who would 'cheat the United States.' *The fraud here could not have been any more of an effort to cheat the United States if there had been no state intermediary*.

Hess, 317 U.S. at 543-44 (emphasis added) (footnotes omitted). Similary, in *United States v. Bornstein*, 423 U.S. 303, 313 (1976), the Supreme Court held that claims generated and submitted by an innocent prime contractor were rendered false under the FCA by the previous actions of a subcontractor.

Moreover, the First Circuit has long ago made clear that its understands *Bornstein* to permit FCA liability for false claims submitted through innocent intermediaries and has recently reaffirmed that point. Thus, in *United States v. Rivera*, 55 F.3d 703, 706-07 (1st Cir. 1995), the First Circuit cited *Bornstein*, 423 U.S. at 309, for the proposition that "a false claim may be presented through an innocent third party." *Id.* (holding that claims for payment generated by an innocent third party arising from a fraud perpetrated on the private lender were false). More recently, in *United States ex rel. Rost v. Pfizer*, 507 F.3d 720 (1st Cir. 2007), the First Circuit also noted this point in reversing the dismissal of a *qui tam* alleging illegal off-label promotion and kickbacks by a pharmaceutical company to physicians that caused false claims to be submitted by innocent pharmacies. In determining that the relator (Rost) should be allowed to amend his complaint, the *Rost* Court explained:

> Under the FCA, Rost must show that Pfizer "cause[d] to be presented" a false claim for payment. 31 U.S.C. § 3729(a)(1). That there were allegedly intervening persons who actually submitted the claims does not itself necessarily break the causal connection when the claims are foreseeable.

Id. (citation omitted).

Similarly, in *United States ex rel. Franklin v. Parke-Davis*, 147 F.Supp.2d 39, 52-53 (D. Mass 2001), Judge Saris rejected the defendant's argument that the relator had not stated a claim because the allegedly false claims for off-label uses of a drug were the result of prescriptions from physicians and the filling of those prescriptions by pharmacists, and, thus, were not caused by the defendant's conduct. Judge Saris explained:

> Under black letter law . . such an intervening force only breaks the causal connection when it is unforeseeable . . . In this case, . . . the participation of doctors and pharmacists in the submission of false Medicaid claims was not only foreseeable, it was an intended consequence of the alleged scheme of fraud.

Id. (citations omitted).

In *United States ex rel. Schmidt v. Zimmer*, 386 F.3d 235 (3rd Cir. 2004), the Third Circuit specifically addressed a defendant's liability for causing the submission of false claims by paying kickbacks. In that case, the Third Circuit held that it is the knowledge and conduct of the defendant (an orthopedic implant supplier alleged to have paid kickbacks to the hospitals presenting the claims) that is relevant to FCA liability. *Schmidt*, 386 F.3d at 244. As explained by the Court in *Schmidt* in addressing very similar allegations:

> It does not appear from the opinion of the Court in either *Hess* or *Bornstein* that the party actually presenting the claims to the government was aware of the fraudulent conduct. This was not a matter material to the Court's analysis, however. . . . [T]he knowledge and conduct of the defendant were what mattered and the outcome did not turn on whether the actual presenters were "duped" or participated in the fraudulent scheme.

Id. at 243-44. In *Schmidt*, the Third Circuit thus reversed the dismissal of the relator's claims that the defendant, a supplier of orthopedic implants, had paid kickbacks that caused hospitals to submit false claims. *Id.* at 244-245.

Likewise here, the fact that BMI may have caused false claims to be submitted through

the actions of hospitals is irrelevant. As long as the submission of the false claims was the forseeable result of its illegal kickbacks, it has caused the submission of false claims and is liable under the FCA. *See Parke-Davis* at 52-53. Thus, in order to give proper effect to the "causes to be presented" prong of the FCA, and consistent with the longstanding proposition that the FCA reaches claims rendered false by one person, but submitted by another individual unaware of the wrongdoing, the *falsity* of the claim is not contingent on the actions or knowledge of the party submitting it.

2. *Thomas's* Holding That Falsity Depends On The Submitting Party's Knowledge Of The Kickback Scheme Must Be Rejected

BMI relies on the decision of the District Court of Arkansas in *United States ex rel. Thomas v. Bailey*, 2008 WL 4853630 (E.D. Ark. Nov. 6, 2008), to argue to the contrary that Relators' FCA counts based on claims submitted by hospitals should be dismissed on the theory that hospitals did not knowingly submit false claims. This argument fails, however, because BMI is alleged to have knowingly caused the submission of those false claims.

The district court in *Thomas* correctly held that compliance with the AKS is "a condition of payment" under the Medicare program. *Id.* at 8. Subsequently, the court found, correctly, that where a party involved in a kickback scheme (in Thomas, the physicians allegedly receiving kickbacks from BMI) submitted claims that resulted from the kickbacks, those claims were "false and fraudulent claims within the meaning of the False Claims Act." *Id.* at *13.[3]

Thomas, however, goes further to hold that claims arising from that same kickback scheme are *not* false or fraudulent merely because they were actually submitted to the government by the

[3] The Amended Complaint in the present case also alleges that physicians received kickbacks from BMI and submitted claims for their services. Thus, these claims clearly survive, even under the analysis of the *Thomas* Court.

innocent hospital, and concludes that a claim that results from a kickback and that is false when submitted by a wrongdoer is laundered into a "clean" claim when an innocent third-party finally submits the claim to the government for payment. *Id.* at *13 ("Thomas has expressly disclaimed any contention that the hospitals violated the Anti-Kickback Statute or knew that [the physician] had done so. Consequently . . . the claims submitted by the hospitals were not false or fraudulent within the meaning of the False Claims Act"). The United States respectfully submits that the *Thomas* decision is simply wrong on this point, and that the decision is contrary to the law in the First Circuit (as set forth above), which recognizes that the FCA creates liability for causing the submission of a false claim through innocent intermediaries.

The *Thomas* Court's approach entirely conflates the FCA's distinct requirements of falsity and knowledge, and renders the latter superfluous. Under such circumstances, liability *would not* lie against the party that submitted the false claim because it lacked knowledge of the falsity. But, liability *would* lie against any person that knowingly caused the false claim to be submitted. Moreover, as discussed above, the plain language of the statute and nearly fifty years of case law make clear that the mere fact that a false claim is submitted through an innocent intermediary does not insulate it from FCA liability.

BMI's argument (*see* BMI's Motion at 12-13) that this Court is bound by the decision of the Arkansas District Court in the *Thomas* case as law of this case must also be rejected. First, as the First Circuit case cited by BMI notes, the "law of the case" doctrine applies to a later decision *in the same case. See Naser Jewelers v. City of Concord*, 538 F.3d 17, 20 (1st Cir. 2008) (holding that district court correctly followed prior ruling by First Circuit in the same case as law of the case). The Court in *Naser* noted, "when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages *in the same case*." *Id.*

(emphasis added). This case, however, is not the same as the *Thomas* action. This case was brought by a different relator, alleging largely different conduct, filed in a different district court. Thus, it is a different case and the "law of the case" doctrine simply does not apply.

In fact, the case at bar is in a different Circuit and governed by different precedent. In the First Circuit, the *Thomas* decision is clearly contrary to applicable precedent, including *Duxbury*, 2009 WL 2450716, and *Rost*, 507 F.3d 720, and, therefore, must not be followed here.

C. BMI's Kickbacks Made The Hospitals' Certifications Expressly False

BMI's payment of kickbacks to physicians who performed services and procedures at the hospital and who chose implants that were then included by hospitals in the hospitals' cost reports to Medicare rendered those cost reports false. The Relators' Amended Complaint notes that hospitals who submit claims to Medicare must submit annual cost reports to the government that state, in part:

> [I]f services identified in this report were provided or procured through the payment **directly or indirectly** of a kickback or were otherwise illegal, criminal, civil and administrative action, fines and/or imprisonment may result.
>
> * * *
>
> . . . I further certify that I am familiar with the laws and regulations regarding the provision of the health care service and **that the services identified in this cost report were provided in compliance with such laws and regulations.**

Amended Complaint, Docket No. 47, at ¶¶ 61-62 (emphasis added).

Courts that have examined this particular certification in the context of kickback allegations have held that it is "false" within the meaning of the FCA whenever services covered by the cost report are tainted by violations of the AKS (even where the hospital submitting the "false" cost reports did not itself receive a kickback). *See Schmidt*, 386 F.3d at 238, n.2, 243 (3d

Cir. 2004). *See also United States ex rel. Thompson v. Columbia/HCA Healthcare*, 20 F. Supp.2d 1017, 1041-42, 1046 (S.D. Tex. 1998). If BMI violated the AKS, then any cost reports that included the procedures involving BMI devices were tainted by kickbacks. Thus, these cost reports would be explicitly and literally "false" within the meaning of the FCA because the services were not "provided in compliance with such laws and regulations."

The fact that it was a non-employee physician working at the hospital who violated the AKS is irrelevant, as that does not change the fact that services were not provided in compliance with the AKS and were therefore false, just as a subcontractor's failure to make a part to specification causes the prime contractor's certification of compliance with specification to be false. *See, e.g., Bornstein*, 423 U.S. at 309 ("It is settled that the [FCA]. . .gives the United States a cause of action against a subcontractor who causes a prime contractor to submit a false claim to the Government"). Thus, on a literal express certification theory, Relators' allegations state a claim under the FCA.

D. Compliance With The AKS Is A Condition Of Medicare Payment, So That Non-Compliance Renders The Claim False Under An Implied Certification Theory

As previously noted, the courts have held that compliance with the AKS is a condition of payment, and the First Circuit has recognized that the violation of a condition of payment, even in the absence of any express certification, is sufficent to render a claim false.[4] *See Duxbury*, 2009 WL 2450716 at *14-15; *Rogan*, 517 F.3d at 452; *Haleyville Medical Supplies*, 423 F.3d at

[4] The First Circuit has long ago upheld FCA liability without requiring any expressly false certification. *See Scolnick v. United States*, 331 F.2d 598 (1st Cir. 1964) (imposing FCA liability based upon mere cashing of check to which payee was not entitled, without any representation to obtain check); *Murray & Sorenson*, 207 F.2d 119, 124 (1st Cir. 1953) (upholding FCA liability where "there was an implied false representation that the bids were at a figure which the corporate defendant would have submitted in competition").

1259-1260; *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F. Supp.2d at 18; *Kneepkins*, 115 F.Supp.2d at 43; *Barrett*, 251 F. Supp.2d at 32-34; *Pogue*, 238 F. Supp.2d at 264. *Cf. Mikes*, 274 F.3d at 699.

BMI contends that the hospitals' cost reports only related to the hospitals' own state of mind, and that the enrollment forms that the physicians signed when becoming Medicare and Medicaid providers contained loopholes that allowed doctors to accept illegal kickbacks without submitting "false" claims. As discussed above, this argument is incorrect as a matter of the language of the express certification, but it also misses the point of the case law and the condition of payment "implied certification" theory entirely. Under the "implied certification" theory, no express certification of compliance with program requirements is required to trigger FCA liability. Instead, one need only show that a condition of payment was violated in order to establish that the claims at issue were false because they were not entitled to be paid.

In the present case, as discussed above, compliance with the AKS is a condition of payment. Accordingly, if the Relators can establish that BMI violated the AKS, they will have established that any claims for Medicare or Medicaid reimbursement that were tainted by those kickbacks were "false" within the meaning of the FCA.

E. <u>DRG Billing Does Not Insulate Kickback Activity</u>

BMI contends that even if the Relators' allegations are true, the fact that BMI paid kickbacks to doctors to induce them to perform spinal surgeries using its products would be immaterial to the government's payment decision. Because hospitals bill the government based upon a diagnostic reimbursement code ("DRG") that is based upon a flat amount for the disease or procedure (including in it the cost of the implant), not for the particular spinal implant separately, BMI contends that there is no false claim. The form of reimbursement, however,

does not insulate BMI from liability for the payment of kickbacks that cause the submission of false claims.

As previously stated, as a matter of law, compliance with the AKS is a condition of Medicare and Medicaid payment, and failure to comply renders the resulting claim false and fraudulent. *See* Section II, A and C of SOI, *supra.* Thus, while it is generally true that when Medicare reimburses providers for spinal surgery, reimbursement for the cost of the devices used in the surgery is incorporated into the reimbursement for the procedure as a whole, this does not render the claim less false. This is no different from the cases in which a faulty component part is fraudulently submitted by a subcontractor and included in a larger product by a prime contractor, after which the government is billed for the whole. *See, e.g.*, *Bornstein*, 423 U.S. at 307 (invoices for radio kits that contained falsely marked electron tubes "included claims for payment for [the] falsely marked tubes"); *United States ex rel. Roby v. Boeing*, 302 F.3d 637 (6th Cir. 2002) (upholding FCA liability and damages for faulty part included in helicopter). The existence of falsity in *any* portion of the claim renders the claim false, and the entity who knowingly caused the false claim to be submitted is liable under the FCA, since the claim being submitted to Medicare would be for services resulting from the payment of a kickback. Such claims would not be subject to reimbursement by Medicare because of their falsity.

This conclusion is supported by sound policy, as well as sound law. When a doctor prescribes a medical device or drug for a patient, the patient has a right to expect that the doctor's recommendation is based solely on his/her medical judgment of what is in the patient's best interests. But, when a company pays kickbacks to a doctor in order to induce him/her to use the company's products, it fundamentally compromises the integrity of this doctor-patient relationship. Moreover, illicit kickbacks can induce doctors to recommend surgery (even when

surgery would not be the best option) or use devices or drugs that are inferior to competing products (or may be less well suited to particular patients), which in turn causes the quality of patient care to suffer. Additionally, when kickbacks induce doctors to opt for more costly treatments, or to prescribe more products or services than they otherwise would, health care costs are inflated, and, if federal health program beneficiaries are involved, taxpayer money is wasted. The Medicare system relies upon physicians to decide what treatment is appropriate and medically necessary for patients, and, therefore, payable by Medicare. As a condition of its reimbursement, Medicare requires that the physicians must render their services without the conflict of receipt of a kickback. Thus, compliance with the AKS is a condition of payment, and a claim tainted by a kickback is false.

F. 9(b) Does Not Mandate That A Relator Must Identify Specific False Claims That Were Submitted To The Government

Despite BMI's argument to the contrary, there is no *per se* rule requiring that specific false claims must be presented in order to satisfy 9(b). *Duxbury*, 2009 WL 2450716 at *14 ("In applying Rule 9(b), the district court held that the rule requires relators to provide details that *identify particular false claims* for payment that were submitted to the government...This was error.") The First Circuit has held that when a defendant engages in a scheme to induce a third party to file false claims (such as the kickback scheme alleged by the Relators in this action), specific examples of false claims are not required to meet 9(b) standards. *Id.* The First Circuit has adopted a more flexible standard, allowing a relator alleging such a scheme to "satisfy Rule 9(b) by providing factual or statistical evidence to strengthen the inference of fraud beyond possibility without necessarily providing details as to each false claim." *Id.* (reversing the lower court's holding that 9(b) requires relators to identify specific examples of false claims submitted

to the government for payment) (internal quotations omitted).

Nontheless, BMI argues that the First Circuit's decision in *Rost*, before the recent *Duxbury* decision, supports its position that the identification of specific claims is required in order to satisfy 9(b). BMI's reliance on Rost is misplaced. While it is true that the complaint in *Rost*, which also alleged a kickback scheme, was dismissed on 9(b) grounds because the relator did not "sufficiently establish that false claims were submitted for government payment in a way that satisfies [9(b)'s] particularity requirement," *Rost*, 507 F.3d at 733, the Court in *Rost* did not go on to hold that a relator *must* identify specific false claims to satisfy 9(b), and *Duxbury* clarified that such claims were not required. *See Duxbury*, 2009 WL 2450716 at *14-17 (holding that 9(b) may be satisfied without the identification of specific claims and discussing the differences between the *Duxbury* and *Rost* complaints).

In the case at bar, the Relators satisfy *Duxbury*'s more flexible standard because they have "alleged the submission of false claims across a large cross-section of providers that alleges the the [sic] who, what, where, and when of the allegedly false or fraudulent representation." *Duxbury*, 2009 WL 2450716 at *16 (internal quotations omitted). The Relators have identified numerous doctors (the "who"), along with their locations (the "where"), who have allegedly received kickbacks (the "what"), including payment under sham consulting agreements and extravagant dinners and entertainment, from BMI, as well as the approximate time frames of the alleged kickbacks (the "when"). *See, e.g.*, Amended Complaint, Docket No. 47, ¶¶ 72-85, 112-131, 152-191, 201-225. Furthermore, Relators have alleged specific facts that create a strong inference of fraud; in making these allegations, Relators have identified specific BMI employees involved in the fraud and specific company documents that arguably acknowledge the kickbacks. *See, e.g.,* Amended Complaint, Docket No. 47, at ¶¶ 82-83, 88-95, 98-110, 112-131, 193, 197

255-258.

Moreover, although not required by *Duxbury*, the Relators in the present case have also identified specific claims (redacted to protect patients' privacy) submitted by three Massachusetts doctors alleged to have received kickbacks from BMI. *See* Amended Complaint, Docket No. 47, at App. 2-A, 2-B, 2-C. BMI makes much ado about these claims being redacted, but this Court should not penalize the Relators for not publicly filing patient–identifying information. In the interests of patient privacy, the United States has requested that such identifying information not be made public. What information should be disclosed to BMI pursuant to an appropriate protective order to protect patient privacy is an issue that the parties can address in the discovery process.

BMI's 9(b) standard, as articulated in BMI's Motion, is all the more inappropriate in the context of an FCA suit based on a violation of the AKS. In this type of case, claims are not rendered false because of anything peculiar to any individual claim. As discussed above, they are false, instead, because they are the result of a kickback. Thus, nothing is gained by requiring the Relators to identify specific claims individually. *See, e.g., United States ex rel. Singh v. Bradford Regional Med. Ctr.*, 2006 WL 2642518 at *7, (W.D. Pa. Sept. 13, 2006) ("The addition of specific identifying information of each claim adds little to complete the description of the scheme since the fraudulent conduct at issue does not rely on any specific claim."). It would not, for example, serve to protect BMI against spurious charges. *Id.* Moreover, so long as the Relators plead the underlying kickback scheme with specificity, and such facts as allow an inference that the resulting claims were submitted to Medicare, BMI has all of the information

necessary to defend the suit.[5]

III. CONCLUSION

Accordingly, based on the foregoing, the United States respectfully submits that BMI's

[5] Should the Court disagree, however, and dismiss this case on 9(b) grounds, such a dismissal should be without prejudice as to the United States, as the government should not be precluded from potentially filing a properly pled complaint consistent with the FCA and the Federal Rules of Civil Procedure. *See, e.g., United States ex rel. Williams v. Bell Helicopter Textron Inc.*, 417 F.3d 450, 456 (5th Cir. 2005) (9(b) dismissal without prejudice to the United States); *United States ex rel. Newsham v. Lockheed Missiles & Space Co.*, 190 F.3d 963, 967 (9th Cir. 1999) (same); *United States ex rel. Pilon v. Martin Marietta Corp.*, 60 F.3d 995, 1000 n.6 (2d Cir. 1995) (same); *Barrett*, 251 F.Supp.2d at 36-37 (same).

Motion be denied.

Respectfully submitted,

UNITED STATES OF AMERICA,

By its attorneys,

MICHAEL K. LOUCKS
Acting United States Attorney

By: /s/ Sonya A. Rao
SONYA A. RAO
SARA MIRON BLOOM
Assistant U.S. Attorneys
John Moakley U.S. Courthouse
1 Courthouse Way, Suite 9200
Boston, MA 02210
(617) 748-3261

TONY WEST
Assistant Attorney General
Civil Division

JOYCE R. BRANDA
MICHAEL GRANSTON
DAVID T. COHEN
Attorneys, Civil Division
United States Department of Justice
Post Office Box 261
Ben Franklin Station
Washington, D.C. 20044
Telephone: (202) 307-1030

DATE: September 2, 2009

CERTIFICATE OF SERVICE

I hereby certify that this document(s) filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent via first-class mail to those indicated as non-registered participants on September 2, 2009.

/s/ Sonya A. Rao
SONYA A. RAO
Assistant U. S. Attorney